UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,743	01/05/2004	Mohamad A. Morsey	16499Z (PC10761B)	3637

23389 7590 03/07/2005

SCULLY SCOTT MURPHY & PRESSER, PC
400 GARDEN CITY PLAZA
SUITE 300
GARDEN CITY, NY 11530

EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,743	MORSEY ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/5/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment, received January 5, 2004 is acknowledged.

Claims 1-41 have been canceled.

Claims 42-51 have been added and are currently pending.

Applicant's amendment to the first line of the specification received on January 5, 2004 is acknowledged. Applicant is reminded to verify and update if necessary the status of applications to which priority has been claimed.

Specification

2. The disclosure is objected to because of the following informalities:

The reference to Helm et al. on page 3, line 7, to Hook et al. on page 4, line 28, and to Hellman on page 6, lines 12 and 15, as well as the CεH2 and CεH3 domain notation on page 3, line 8 should be capitalized. Additionally, Example 1 on page 32 should be corrected to indicate KLH at all occurrences of KLh. Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47 is dependent upon claim 46, wherein claim 46 recites a composition that comprises a fusion protein consisting of the CH3 domain of an IgE molecule **and** a heterologous carrier protein. Claim 47 further limits the claim in that the fusion protein consists of SEQ ID NO:4. SEQ ID NO:4 is a CH3 domain peptide sequence that does not contain sequence of a heterologous fusion protein. As such, it appears that no fusion protein exists in claim 47 since SEQ ID NO:4 is not fused to anything. Appropriate amendment of claim 47 to clarify the structure of the pharmaceutical composition is required.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 44, 46, 48, and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant has claimed compositions containing peptides that comprise the CH3 domain of an IgE molecule, and as such the breath of the claim reads on *any* CH3 domain obtained from *any* organism. Applicant has disclosed peptides corresponding to the CH3 domains of dogs and humans.

The prior art teaches that the constant region of IgE is the least well conserved across species of the five isotypes of immunoglobulins (Hollis et al., US Patent No. 5,629,415, see entire document particularly column 1, lines 55-60 and Figure 2). It was known in the prior art that the residues of IgE that are important for binding to receptors on mast cells and basophils are located in the CH3 and CH4 domains of IgE (see Hollis et al., particularly the paragraph that spans columns 1 and 2). One peptide isolated from human IgE that was shown to inhibit passive sensitization by occupying the Fcε receptor sites present on human cells was only 50% identical to a peptide from the corresponding position of canine IgE, and as such it is desirable to use species-specific reagents in therapeutic attempts to modulate allergic reactions (see Hollis et al., particularly the paragraph that spans columns 1 and 2, and column 2, lines 30-50).

No definition of the structure required by polypeptides to be considered CH3 peptides appears to be disclosed in the specification. Without a definition of the

structure of the CH3 domain of IgE, it is impossible to describe the structural characteristics of the genus CH3 domain peptides from all species. This is especially so in light of the teachings of the prior art which indicate the relative lack of amino acid sequence conservation among species with respect to the constant domains of IgE. Therefore, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus of all IgE CH3 peptides from all organisms. Thus, Applicant was not in possession of the claimed genus of all peptides comprising a CH3 domain of IgE from any species. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 42 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollis et al. (US Patent No. 5,629,415, see entire document).

Hollis et al. disclose the polynucleotide and amino acid sequence of the constant region of canine IgE, said sequence comprising SEQ ID NO:4 of the instant application (see entire document, particularly Figure 1). Hollis et al. describe that therapeutically interesting portions of the disclosed sequences can be expressed in chimeric proteins or used to produce peptides that are to be used in vaccines to prevent or treat IgE mediated hypersensitivity or as reagents in the production of monoclonal or polyclonal antibodies (see particularly column 2, lines 50-61, Examples 5, 10, and 11). It is also disclosed that an IgE specific antibody response can be obtained by immunizing animals with canine IgE, said canine comprising SEQ ID NO:4 (see particularly column 7, lines 52-67, column 8, lines 1-48, and Examples 5, 10, and 11). Hollis specifically indicates the importance of the IgE CH3 and CH4 domains in binding to receptors, and indicate that the methods disclosed for the production of antibodies applies to making antibodies specific for canine IgE polypeptide fragments as well as full length canine IgE polypeptide (see particularly column 1, lines 46-54, the paragraph that spans columns 1 and 2, and column 8, lines 45-48). The recombinant forms of canine IgE disclosed by Hollis are also present in kits to facilitate forensic analyses and epidemiological studies (see particularly the paragraph that spans columns 8 and 9 and Example 11).

The comprising language currently recited in the claims allows for the incorporation of additional sequence, and as such the full length canine IgE and canine IgE chimeric proteins disclosed by Hollis et al. meet the structural limitations of the claimed product. Therefore, functional limitations, such as the inability to cause anaphylaxis, are inherent properties of the prior art product unless it can be

demonstrated that the product of the prior art does not have the same functional properties. See In re Best, 195 USPQ 430 (CCPA 1977), and MPEP 2112.

Therefore, the teachings of the prior art anticipate the claimed invention.

9. Claims 42, 43, 44, 46, 49, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Mermer et al., WO 97/30156 (see entire document).

Mermer et al. teach the sequence of canine IgE heavy chain constant region and methods of its use (see entire document, particularly the abstract). The sequence disclosed by Mermer et al. as canine IgE heavy chain comprises SEQ ID NO:4 of the instant application. Mermer et al. disclose a fusion protein that has 64 amino acid residues of canine IgE CH3 joined to the heterologous carrier protein β-galactosidase (see particularly the section titled Expression of Recombinant IgE Heavy Chain Constant Region Proteins in *E. coli* from pages 19 to 22, most particularly the paragraph that spans pages 21 and 22) as well as other constructs that contain sequences of varying length that comprise SEQ ID NO:4 (see particularly Examples 2-8, pages 24 to 32). Mermer et al. further disclose recombinant IgE molecules in pharmaceutical compositions for use producing monoclonal antibodies and in therapeutically vaccinating dogs that experience allergic disease (see particularly Examples 2 to 8).

The comprising language currently recited in the claims allows for the incorporation of additional sequence, and as such the full length canine IgE and canine IgE chimeric proteins disclosed by Mermer et al. meet the structural limitations of the

claimed product. Therefore, functional limitations, such as the inability to cause anaphylaxis, are inherent properties of the prior art product unless it can be demonstrated that the product of the prior art does not have the same functional properties. See In re Best, 195 USPQ 430 (CCPA 1977), and MPEP 2112.

Therefore, the prior art anticipates the claimed invention.

10. Claims 42, 43, 44, 46, and 48-50 are rejected under 35 U.S.C. 102(a) as being anticipated by Wang et al., WO 99/67293 (see entire document, of record on form 1449 received 1/5/04).

Wang et al. teach the use of canine CH3 peptides in pharmaceutical compositions for immunotherapy of IgE mediated allergic diseases (see entire document, particularly the abstract and page 1, lines 5-24). The CH3 domain of IgE is important because it is involved in the binding of IgE to receptors on basophils and mast cells (see particularly page 3, lines 24-34 and page 6, lines 6-10). As such, Wang et al. disclose synthetic peptide compositions that either comprise SEQ ID NO:4 (see particularly SEQ ID NO:2 of Wang et al.) or consist of fragments of SEQ ID NO:4 of the instant invention (see particularly pages 20-22, Tables 1 and 2, and SEQ ID NOs: 5, 6, 44, 55, 58, 87, 88, and 90 of Wang et al. which contain fragments of SEQ ID NO:4 of the instant invention). These peptides can be linked to carrier proteins, such as KLH, to increase immunogenicity (see particularly page 22, lines 10-22 and page 27, lines 3-23). Since SEQ ID NO:4 of the instant invention is a CH3 domain peptide of canine IgE,

and Wang et al. disclose multiple peptides that contain subsequences of SEQ ID NO:4 of the instant invention, the sequences of Wang et al. are fragments of a CH3 domain.

The comprising language currently recited in the claims allows for the incorporation of additional sequence, and as such the peptides and chimeric proteins disclosed by Wang et al. meet the structural limitations of the claimed product. Therefore, functional limitations, such as the inability to cause anaphylaxis, are inherent properties of the prior art product unless it can be demonstrated that the product of the prior art does not have the same functional properties. See In re Best, 195 USPQ 430 (CCPA 1977), and MPEP 2112.

Therefore, the teachings of the prior art anticipate the claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mermer et al., WO 97/30156 (see entire document) in view of Harlow et al. (Antibodies, A Laboratory Manual, page 129).

The teachings of Mermer et al. have been discussed above. These teachings differ from the claimed invention in that Mermer et al. do not disclose the use of a carrier protein with their IgE CH3 domain containing polypeptides.

Harlow et al. teach that the immunogenicity of a polypeptide can be increased by coupling it to a carrier protein. One particularly useful carrier protein disclosed by Harlow et al. is keyhole limpet hemacyanin (KLH).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the peptides taught by Mermer et al. to include a carrier peptide as taught by Harlow et al. Motivation to make this modification comes from the teaching of Harlow et al. that carrier proteins increase the immunogenicity of the polypeptide sequence to which they are attached.

13. Claims 44, 46, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mermer et al., WO 97/30156 (see entire document) in view of Hollis et al. (US Patent No. 5,629,415, see entire document).

The teachings of Mermer et al. have been discussed above. These teachings differ from the claimed invention in that Mermer et al. do not disclose the use of their IgE CH3 domain containing polypeptides in kit form.

Hollis et al. teach that it is desirable to have kits containing canine IgE polypeptides for use in forensic analyses and epidemiological studies (see particularly the paragraph that spans columns 8 and 9).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to place the polypeptides of Mermer et al. into a kit form as taught by Hollis et al. Motivation at the time the invention was made to make such a modification comes from the teaching of Hollis et al. that kits containing IgE polypeptides are to be used in performing forensic analyses and epidemiological studies.

14. Claims 44, 46, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al., WO 99/67293 (see entire document, of record on form 1449 received 1/5/04) in view of Hollis et al. (US Patent No. 5,629,415, see entire document).

The teachings of Wang et al. have been discussed above. These teachings differ from the claimed invention in that Wang et al. do not disclose the use of their IgE CH3 domain containing polypeptides in kit form.

Hollis et al. teach that it is desirable to have kits containing canine IgE polypeptides for use in forensic analyses and epidemiological studies (see particularly the paragraph that spans columns 8 and 9).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to place the polypeptides of Wang et al. into a kit form as taught by Hollis et al. Motivation at the time the invention was made to make such a modification comes from the teaching of Hollis et al. that kits containing IgE polypeptides are to be used in performing forensic analyses and epidemiological studies.

Double Patenting

15. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

16. Claims 45 and 47 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 7 of copending Application No. 09/938,700. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The scope of dependent claims 45 and 47 of the instant application is limited to a pharmaceutical composition comprising a peptide that consists of SEQ ID NO:4. It is noted that while claim 47 recites a fusion protein, the "fusion protein" recited appears to consist of SEQ ID NO:4 and nothing else. Claim 7 of copending Application No. 09/938,700 is also limited a pharmaceutical composition comprising a peptide that consists of SEQ ID NO:4. SEQ ID NO:4 is the same sequence in both applications. The claims in both cases are limited to a peptide that consists of the same sequence and both recite the same functional limitation of not inducing anaphylaxis upon administration. As such, the scope of the claims are identical.

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 42-44, 46, and 48-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 7, 9, 11 and 41 of copending Application No. 09/938,700. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in copending Application No. 09/938,700 anticipate the instant claims since the claims of copending Application No. 09/938,700 are narrower in scope than the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 42, 43, 44, 46, 48, 49, and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 6, 8, and 19-23 of copending Application No. 10/152,190. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application No. 10/152,190 anticipate the instant invention. Specifically, SEQ ID NO:2, 3, 10, 11, and 12 of copending Application No. 10/152,190 comprise SEQ ID NO:4 of the instant invention. The comprising language of instant claims 42, 43, 44, 46, 48, 49 and 50 allow for additional sequence on either end of SEQ ID NO:4, and thus the polypeptides identified by SEQ ID NO:2, 3, 10, 11,

and 12 in claims 5, 6, 8, 20, and 22 of copending Application No. 10/152,190 anticipate the claimed invention.

The scope of the claims is not identical since instant claims 42 and 43 can comprise additional sequences that are shorter or longer than the sequences disclosed in copending Application No. 10/152,190. The same analysis hold for claims 44, 46, and 48 drawn to pharmaceutical compositions as they anticipate claims 19-23 copending Application No. 10/152,190.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. No claims are allowable.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Szperka, Ph.D.
Patent Examiner
Technology Center 1600
March 3, 2005

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600